REMARKS

Claims 21, 22, 24, and 28-55 are pending in this application. Claims 21, 28, 30, 31, 32, and 38 have been amended. Claims 1-20, 23, and 25-27 have been cancelled. Support for the amendments is found in the specification and claims as filed.

Interview

Applicants thank Examiner Nasser for the courteous and helpful interview conducted with Applicants' representative, Laura Johnson, on August 1, 2003.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 21, 22, 24, and 28-55 have been rejected under 35 U.S.C. § 112, first paragraph, as including new matter by reciting that the second domain is resistant to cellular attachment. Applicant has amended the claims to delete this recitation.

Claims 21, 22, 24, and 28-55 have been rejected under 35 U.S.C. § 112, first paragraph, as including new matter by reciting that the second domain is impermeable to cells and cell processes. The claims have been amended to recite that the second domain is impermeable to macrophages. Support for the amendment is found on page 20, lines 5-8 of the specification as filed. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 21, 22, 24, and 28-55 have been rejected under 35 U.S.C. § 112, second paragraph as indefinite in regard to the spatial relationship of the first domain and the sensing membrane. The claims have been amended to clarify the spatial relationship. The specification as filed, page 8, lines 3-9, explains in detail how spatial relationships are defined within the context of the application. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a)

Claims 21, 22, 24, 28, 44, 45, 50, and 51 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shulman et al. in view of Picha. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, if the proposed modification would render the prior art invention

being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Schulman et al. disclose an implantable enzyme-based glucose monitoring system small enough to be implanted through the lumen of a catheter or hypodermic needle, that measures the amount and rate of change of glucose in a patent's blood over an extended period of time (col. 1, lines 5-15). Schulman's disclosed sensor is particularly designed for sensing blood glucose intravascularly (in contrast to subcutaneously) as noted by the "window formed with smooth tapered surfaces or edges, thereby maintaining a controlled uniform flow of blood over the window while preventing any stagnation of blood near the window and thereby minimizing the formation of blood clots" (col. 7, lines 19-23). Additionally, Schulman et al. disclose a preferred embodiment wherein "some or all of the exterior surface of the monitoring system has an exterior coating applied thereto that includes an anti-coagulant and/or anti-tissue growth solution" (col. 7, lines 60-64). Picha teaches a sensor device implanted in the soft tissue that includes the use of foam on the surface of the implant to enhance fixation of the implant in soft tissue and to increase vascular ingrowth (see Fig. 8 and related text).

The Office Action asserts that it would have been obvious to modify the Schulman et al. sensor to use an outer layer as taught by Picha to extend its useable life. However, the foam outer layer of Picha, which increases vascular ingrowth, would cause coagulation or tissue ingrowth around the sensor of Shulman et al., which is specifically designed for intravascular use and not subcutaneous use. Shulman et al. teaches that such coagulation and tissue ingrowth is undesirable, and specifies that anti-coagulant and/or anti-tissue growth solution can be coated onto the exterior surface of the monitoring system to avoid coagulation and tissue ingrowth. As is appreciated by one skilled in the art, coagulation on an intravascular device can lead to the formation of blood clots, which can in turn cause stroke or pulmonary embolism.

Accordingly, if the sensor disclosed in Shulman et al. is modified by adding a foam surface covering as disclosed in Picha, the Shulman et al. sensor will not be suitable for use in sensing glucose intravascularly. A *prima facie* case of obviousness therefore cannot be made, and Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a)

Claims 29-33, 38-39, 41-43, 46-49, and 52-55 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Schulman et al. in view of Picha and Ward et al.

As discussed above, the Shulman et al. sensor will be unsuitable for its intended use if modified according to the teachings of Picha. The teachings of Ward et al. do not address the deficiencies discussed above. Accordingly, Applicants respectfully request withdrawal of the rejection..

Allowable Subject Matter

Applicants gratefully acknowledge the Examiner's indication of allowability with respect to Claims 34-37 and 40, if rewritten to overcome the rejections under 35 USC §112, second paragraph, and to include all of the limitations of the base claim and any intervening claims. The rejections under 35 USC §112, second paragraph, have been addressed as discussed above.

Conclusion

Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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Dated: 8/5/03

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